K131181

510(k) Summary

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Trade Name: Omega Laboratories Hair Drug Screening Assay Phencyclidine

Common Name: Hair Drug Screening Assay Phencyclidine

Applicant:

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Table 1: Classification Information

Classification or descriptor	Name or designation
Trade Name	Omega Laboratories Hair Drug Screening Assay Phencyclidine
Common Name	Hair Drug Screening Assay for Phencyclidine (PCP)
Classification Name	Enzyme immunoassay, phencyclidine
Classification Panel	91 (Toxicology)
Product Code	LCM
Regulation Number	Unclassified, Enzyme Immunoassay, PCP

All questions and/or comments concerning this document should be made to:

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1.0 ASSAY SUMMARY

The Assay is an enzyme immunoassay for the qualitative detection of phencyclidine in head and body hair (hair). Phencyclidine (PCP), the hallucinogen commonly referred to as Angel Dust, can be detected in hair.

The assay consists of two parts; a pre-analytical proprietary and patent pending hair treatment procedure (to remove PCP from the solid hair matrix to a measurable liquid matrix), and the screening assay. The screening assay is an Enzyme-Linked ImmunoSorbent Assay (ELISA).

After the extraction treatment, the test sample is added to a well of the coated micro strip plate and enzyme conjugate is added, followed by incubation. During this phase the enzyme-labeled drug conjugate competes with drug in the sample for a limited number of binding sites on the antibody-coated micro wells. The two bind in proportion to their concentrations. A wash solution is applied to remove any unbound materials. Enzyme substrate solution containing a chromagen is added. The reaction is stopped with an acid and the absorbance is read using a plate reader at 450 nm. A background reading is also taken at 630 nm. Color intensity is inversely proportional to the amount of drug present in the sample. For the screening of PCP in hair, an enzyme linked immunosorbent assay (ELISA) procedure has been established.

2.0 PREDICATE DEVICES

Omega Laboratories Hair Drug Screening Assay Phencyclidine (k101059)

3.0 INTENDED USE AND INDICATIONS FOR USE

The Omega Laboratories Hair Drug Screening Assay Phencyclidine is an in vitro diagnostic test that is intended to be used for the determination of the presence of PCP in human hair from the head and body. The Omega Laboratories Hair Drug Screening Assay utilizes an enzyme linked immunosorbent assay (ELISA) for PCP, for the qualitative detection of PCP at or above 300 pg/mg of hair for the purpose of identifying the use of PCP. To confirm a screen positive result, a more specific alternate chemical method, such as Gas Chromatography/Mass Spectrometry (GC/MS) operating in the selected ion monitoring (SIM) mode is the preferred method with deuterated internal standards. Professional judgment should be applied to any drug of abuse test result, particularly when presumptive positive results are obtained.

This test is intended exclusively for single laboratory use only and is not intended for sale to anyone.

4.0 ASSAY DESCRIPTIONS

4.1 The Omega Laboratories Hair Drug Screening Assay Phencyclidine is a test system that utilizes an ELISA PCP reagents and a micro-plate reader for the qualitative detection of Phencyclidine in head or body hair samples at or above 300 pg/mg. It is an assay intended exclusively for single laboratory use by trained laboratory personnel only and is not intended for sale to anyone. This is a qualitative assay and the performance at low concentrations was evaluated in the precision studies.

4.2 The Omega Laboratories Hair Drug Screening Assay Phencyclidine screening test provides only a preliminary analytical test result. To confirm a screen positive result, a more specific alternate chemical method must be used.

4.3 Assay

4.3.1 The test consists of two parts; a pre-analytical proprietary and patent pending hair treatment procedure (to convert the solid matrix of hair to a measurable liquid matrix), and the screening assay.

4.4 Specifications

4.4.1 Donor Sample Collection

4.4.1.1 Donor samples are collected using the Omega Collection Kit. Hair samples stored in the Kit have a one year shelf life.

4.4.2 ELISA PCP (microplate format)

4.4.2.1 The PCP assay utilizes an enzyme-linked immunosorbent assay technology (ELISA). ELISA utilizes highly sensitive and specific (polyclonal goat) antibodies onto a solid-phase surface such as a microwell plate. The sample to be tested competes with an enzyme solution for the binding sites of the antibody. If the enzyme binds to the antibody, a color change occurs after the addition of substrate. The darker the color, the lower the amount of analyte in the sample.

4.5 Materials

4.5.1 Sample Collection Kit

4.5.2 ELISA PCP microplate, reagents, controls

4.5.3 Micro Plate Reader

5.0 COMPARISON OF OMEGA LABORATORIES PCP ASSAY AND ITS PREDICATES

Table 2: Comparison of Omega Laboratories PCP Assay vs Omega Laboratories Hair Drug Screening Assay Phencyclidine (PCP) k101059

Comparison Element	Omega Laboratories Hair Drug Screening Assay Phencyclidine (k131181)	Omega Laboratories Hair Drug Screening Assay Phencyclidine K101059
Laboratory	Omega Laboratories, Inc.	Omega Laboratories, Inc.
Indication for/ Intended Use	The Omega Laboratories Hair Drug Screening Assay Phencyclidine is an in vitro diagnostic test that is intended to be used for the determination of the presence of PCP in human hair from the head and body. The Omega Laboratories Hair Drug Screening Assay (PCP) utilizes an enzyme linked immunosorbent assay (ELISA) for PCP, for the qualitative detection of PCP at or above 300 pg/mg of hair for the purpose of identifying the use of PCP. To confirm a screen positive result, a more specific alternate chemical method, such as Gas Chromatography/Mass Spectrometry (GC/MS) operating in the selected ion monitoring (SIM) mode is the preferred method with deuterated internal standards. Professional judgment should be applied to any drug of abuse test result, particularly when presumptive positive results are obtained. This test is intended exclusively for single laboratory use only and is not intended for sale to anyone.	Same
Product Code	LCM	Same
Measurand	Phencyclidine (PCP)	Same
Method of Measurement	Microplate reader. Read at 450 nm	Same
Matrix	Head and body hair	Head hair
Cutoff concentration	300 pg PCP/mg hair	Same
Type of Test	ELISA (polyclonal goat antibodies)	Same

Table 2: Comparison of Omega Laboratories PCP Assay vs Omega Laboratories Hair Drug Screening Assay Phencyclidine (PCP) k101059

Comparison Element	Omega Laboratories Hair Drug Screening Assay Phencyclidine (k131181)	Omega Laboratories Hair Drug Screening Assay Phencyclidine K101059
Extraction Method	Acid-methanol to facilitate extraction of PCP from hair.	Same

6.0 SUMMARY OF PERFORMANCE TESTING

6.1 Precision Study

6.1.1 The Precision Study was performed to evaluate the intra and inter-assay precision/reproducibility of the Protocol using head hair samples.

Intra-assay Precision using individual samples was performed to characterize precision when replicate measurements of single hair samples were analyzed. Five hair specimens previously found to be positive for PCP were analyzed. Each hair specimen was divided into 6 aliquots of approximately 20 mg each. Three aliquots were treated and analyzed in the same manner as donor hair samples and measured in one run.

Table 3: Intra-Assay Precision of Individual Replicates Studies

Drug	Concentration of Sample (pg/mg)	Number of Replicates	Results # Negative	Results # Positive
PCP	399	3	0	3
PCP	560	3	0	3
PCP	1435	3	0	3
PCP	4528	3	0	3
PCP	7096	3	0	3

Intra-assay precision studies were performed using 11 replicates of negative hair samples spiked to the following concentrations of PCP: zero drug, -75%, -50%, -25% below the cutoff, and +25%, +50%, +75% and +100% above the cutoff. All samples were treated and analyzed in the same manner as donor hair samples and measured in one run.

Table 4: Intra-Assay PCP Precision Studies (CO=300 pg/mg)

Drug	Concentration of Sample (pg/mg)	Number of Replicates	Results # Negative	Results # Positive
PCP	0	11	11	0
PCP	75	11	11	0
PCP	150	11	11	0
PCP	225	11	11	0
PCP	375	11	0	11
PCP	450	11	0	11
PCP	525	11	0	11
PCP	600	11	0	11

n = 11 for each concentration

Inter-assay precision studies were performed using negative hair samples spiked to the following concentrations of PCP: zero drug, -75%, -50%, -25% below the cutoff, and +25%, +50%, +75% and+100% above the cutoff.

All samples were treated and analyzed in the same manner as donor hair samples. Eleven replicates of these were prepared and analyzed over 20 non-consecutive days.

Table 5: Inter-Assay PCP Precision Studies (CO=300pg/mg)

Drug	Concentration of Sample (pg/mg)	Number of Replicates	Results # Negative	Results # Positive
PCP	0	220	220	0
PCP	75	220	220	0
PCP	150	220	220	0
PCP	225	220	220	0
PCP	375	220	0	220
PCP	450	220	0	220
PCP	525	220	0	220
PCP	600	220	0	220

N = 220 for each concentration

6.2 Agreement Study

6.2.1 The original Agreement Study (k101059) was performed by comparing ELISA results against quantitative GC/MS confirmatory results on the same hair specimens. A total of 352 donor hair samples were tested in this study. See k101059 (OLSR10).

6.2.2 A second study was conducted to support the use of the PCP assay with body hair in addition to the already cleared head hair. A total of 41 specimens were added to the existing Agreement (OLSR10 Rev 2) for a total of 393 specimens (Negative n=177 and Positive n=216)

Table 6: Summary of Agreement Study Results Head and Body Hair (n=393)

ELISA Test Result	GC/MS Negative (< 50 pg/mg)	GC/MS Negative (<150 pg/mg)	GC/MS Negative (150 - 299 pg/mg)	GC/MS Positive (300 - 450 pg/mg	GC/MS Positive (>450 pg/mg)
Positive	0	1	15	38	162
Negative	150	15	8	4	0

Table 7: GC/MS Summary of Discordant Results [n = 20 head and body hair samples]

Screening Cutoff (pg/mg)	ELISA PCP Test Result (POS/NEG)	GC/MS Cutoff (pg/mg)	GC/MS Drug Result (Total PCP Equivalents pg/mg)	Associated Crossreacting Compound
300	POS	300	122	The presence of the structurally similar compounds metaphit, 4-hydroxyphencyclidine, and phencyclidine morpholine may contribute to a PCP positive ELISA
300	POS	300	166	
300	POS	300	184	
300	POS	300	264	
300	POS	300	267	
300	POS	300	272	
300	POS	300	280	
300	POS	300	284	
300	POS	300	286	
300	POS	300	287	
300	POS	300	287	
300	POS	300	288	
300	POS	300	290	
300	POS	300	291	
300	POS	300	293	
300	POS	300	298	
300	NEG	300	301	NA
300	NEG	300	301	
300	NEG	300	305	
300	NEG	300	313	

6.3 Cosmetic Treatment Study

6.3.1 The Cosmetic Treatment study documented the effects of various cosmetic treatments on the Omega Laboratories, Inc. ELISA PCP Screening Protocol using head hair.

Table 8: Hair Treatment Assignment
(n = 176 head hair samples)

BLEACH 1
BLEACH 2
PERM 1
PERM 2
DYE 1
DYE 2
RELAXER 1
RELAXER 2
SHAMPOO 1
SHAMPOO 2

Table 9: Effects of Hair Treatments on Negative Samples (ELISA Assay) n=86

Treatment	Shampoo #1	Shampoo #2	Perm #1	Perm #2	Dye 1	Dye 2	Bleach #1	Bleach #2	Relaxer #1	Relaxer #2
Mean Abs. Untreated Hair	1.858	1.728	1.810	1.605	1.828	1.727	1.810	1.719	1.699	1.742
Mean Abs. Treated Hair	1.841	1.743	1.767	1.613	1.855	1.718	1.830	1.800	1.693	1.738
Mean Change	-0.017	0.015	-.043	0.008	0.026	-0.009	0.020	0.081	-0.006	-0.004

Table 10: Effects of Hair Treatments on Positive Samples (ELISA Assay) n=89

Treatment	Shampoo #1	Shampoo #2	Perm #1	Perm #2	Dye 1	Dye 2	Bleach #1	Bleach #2	Relaxer #1	Relaxer #2
Mean Abs. Untreated Hair	0.452	0.417	0.250	0.465	0.468	0.442	0.359	0.331	0.417	0.505
Mean Abs. Treated Hair	0.473	0.445	0.279	0.526	0.485	0.456	0.354	0.326	0.441	0.547
Mean Change	0.023	0.029	0.029	0.061	0.016	0.015	-0.005	-0.005	0.024	0.042
Change POS to NEG	0/17		3/18		2/18		0/18		1/18	

6.3.2 Permanent treatments saw the greatest effect on positive samples (3 of 18 became negative after treatment); followed by Dye (2 of 18 becoming negative after treatment) and then Relaxer (1 of 18). All other treatment types saw no change in

assay results (6 of 89 samples reported a change from positive to negative as a result of the treatment.

6.4 Cross reativities

Cross Reactivity and Interference studies were conducted to evaluate the specificity of the Omega Laboratories, Inc. ELISA PCP Screening Protocol and the possible effect of interfering compounds using head hair.

6.4.1 The study demonstrated that the presence of the structurally similar compounds metaphit, 4-hydroxyphencyclidine, and phencyclidine morpholine may contribute to a PCP positive ELISA result when utilizing this protocol. None of the other (270) compounds demonstrated interference with the ELISA PCP protocol.

Table 11. Crossreactivity of Phencyclidine ELISA with Structurally Similar Compounds

Compound	Approximate Concentration of Compound (pg/mg) Equivalent to 300pg/mg Phencyclidine Cutoff Control (n=3)	Percent Crossreactivity (%)
Phencyclidine	300	100
Metaphit	500	60.0
4-Hydroxy-Phencyclidine	6000	5.0
Doxylamine	40000	Did not produce a result
Phencyclidine Morpholine	1500	20.0

6.5 Environmental Contamination

Preliminary positive hair sample results by the screening method could be due to environmental contamination. All positive samples should be sent for confirmation testing on a reference method to distinguish between true positives and those that were positive due to external exposure.

6.6 Calibrator and Control

6.6.1 The in-house calibrator and control solutions are prepared solely for use within Omega and only at its laboratories in Mogadore, OH.

6.6.2 The study demonstrated the stability of PCP in methanol for a period of one year when stored refrigerated in an amber bottle is also attached. This validates the one 1 year expiration date for the PCP Calibrator Stock Solution

6.7 Recovery Study

6.7.1 The Extraction Recovery Study evaluated the effectiveness of the extraction method utilized by the Omega Laboratories, Inc. ELISA PCP Screening Protocol.

6.7.2 Five head hair samples that previously confirmed positive for PCP were used for these studies. Samples were aliquoted in duplicate: one aliquot was taken through the acidic-methanol extraction and the other was taken through the 100% recovery extraction.

6.8 Shipping Study

6.8.1 The Shipping Study was conducted to determine whether there is any adverse effect on donor hair samples when exposed to extreme temperatures and variations in humidity that might occur during sample shipments.

6.8.2 137 head hair samples were used in the shipping study; 30 previously confirmed Positive samples, 100 previously screened negative samples and 7 samples that were just under the cutoff. Each box contained a variety of hair color and curvature. Four separate shipping boxes each containing 25 previously screened Negative samples; at least 7 previously confirmed Positive samples and at least 2 samples close to cutoff were stored in a freezer over night then heated for a period of at least four hours. The minimum and maximum temperature and humidity ranges are in Table S1 below. Each box was then shipped to a different location in the United States of America. (Portland, Maine, Anchorage, Alaska, Naples, Florida and Tempe, Arizona). The shipments were held at their respective locations for a period of at least two days then returned to Omega.

6.8.3 The average mean % of change in result prior to shipping and after shipping was 0% for all locations combined. The study demonstrated that because a hair sample is a solid matrix, it is not susceptible to the same temperature constraints as a urine sample. All negative sample remained negative after shipping. Of the Positive and near Positive samples, two pre-shipping samples that screened negative, screened positive after shipping. Of the pre-shipping positive screen, two samples screened negative after shipping.

6.9 Stability Study

6.9.1 The Stability Study was conducted to determine whether there are any adverse effects on the level of PCP contained in a hair sample when it is placed in storage for an extended period of time.

Table 12: Stability values (n = 137 head hair samples)

Measured value	**Value or range**
Range in concentration pg/mg hair (Before)	110 - 4999
Range in concentration pg/mg hair (After)	115 - 5102
Mean Change	-8%
% Max and Min Decrease	-32% and -2%
% Max and Min Increase	9% and 2%
Number that increased in concentration	8
Number that decreased in concentration	12

Based on the 8 % mean percent change over the 2.5 year storage, donor sample PCP drug stability is maintained. Shelf life for the hair samples has been set at 1 year after collection.

7.0 Conclusion:

The Omega Laboratories Hair Drug Screening Assay Phencyclidine using both head and body hair does not raise any new safety and efficacy concerns when compared to the cleared Omega Assay for Phencyclidine (PCP) using head hair only.

Based on the design and performance test results, the Omega assay is substantially equivalent to the predicate Phencyclidine (PCP).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 25, 2013

Omega Laboratories, Inc.
C/O Robert J. Bard, JD
Managing Director
400 North Cleveland
MOGADORE OH 44260

Re: K131181
Trade/Device Name: Omega Laboratories Hair Drug Screening Assay Phencyclidine
Regulation Number: 21 CFR 862.3100
Regulatory Class: Unclassified
Product Code: LCM
Dated: February 23, 2013
Received: April 25, 2013

Dear Mr. Bard:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson -S for

Courtney H. Lias, Ph.D.
Director, Division of Chemistry and Toxicology
Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number: k131181

Device Name: Omega Laboratories Hair Drug Screening Assay Phencyclidine

Indications for Use:

The Omega Laboratories Hair Drug Screening Assay Phencyclidine (PCP) is an in vitro diagnostic test that is intended to be used for the determination of the presence of PCP in human hair from the head and body. The Omega Laboratories Hair Drug Screening Assay (PCP) utilizes an enzyme linked immunosorbent assay (ELISA) for PCP, for the qualitative detection of PCP at or above 300 pg/mg of hair for the purpose of identifying the use of PCP. To confirm a screen positive result, a more specific alternate chemical method, such as Gas Chromatography/Mass Spectrometry (GC/MS) operating in the selected ion monitoring (SIM) mode is the preferred method with deuterated internal standards. Professional judgment should be applied to any drug of abuse test result, particularly when presumptive positive results are obtained.

This test is intended exclusively for single laboratory use only and is not intended for sale to anyone.

Prescription Use _____ (21 CFR Part 801 Subpart D)	And/Or	Over the Counter Use __X__ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Denise Johnson-lyles -S
2013.06.25 10:55:51 -04'00'

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) k131181